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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,323	03/20/2000	STEFAN SANNER	258.00040101	2155

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-13

Office Action Summary	Application No.		Applicant(s)	
	09/446,323		SANNER, STEFAN	
	Examiner		Art Unit	
	P. Kathryn Bex		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-18 and 23 is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 10-12, 19, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2003 has been entered.
2. The addition of claims 22-23 is acknowledged and has been entered into the record.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, (e.g. "means"), should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. For example, the instant abstract recites "a testing means 40", "sample taking means", etc. This legal phraseology must be eliminated.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 8, 11-12, 19-20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith *et al* (USP 4,534,939).

Smith *et al* discloses a device for self-contained coagulation detection. The device comprising a housing 24 in which a cartridge 52, testing means 74 and sample taking means 102 are positioned. The cartridge containing activator reagent. The activator agent 52 is preferably retained substantially within an enclosure defined by an inverted cup-shaped structure 54. The activator agent 52 is thereby confined between the inverted cup-shaped structure 54 and the partition 38. The cup-shaped structure 54 is glued or otherwise fastened to the interior surface of the lower portion 48 by a spot of adhesive 56. The testing means is a chamber defined by 60 and partition 38. The sample taking means comprising a syringe which inherently includes a chamber. Additionally, the cartridge and testing means are displaceable within the housing via nozzle member 112 such that the cartridge and testing means are brought into contact with the sample mixture for analyzing this mixture (Figs. 11-16).

6. Claims 1-3, 8, 11-12, 19-20, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hessel *et al* (USP ~~4,534,939~~ ^{6,048,735}).

Hessel *et al* discloses a multisectioned fluid delivery device for immunoassay detection. The device comprising a housing 6 in which a plurality of cartridges 8, testing means 1 and sample taking means (e.g. inside cap 16) are positioned. The biological sample is placed in the cap and the cap is fitted onto the distal end of the syringe portion 9. The testing means is a sensor laminate 1 and permits binding of any target molecule in the sample to the reactive substrate layer 3 of the sensor laminate. The turning handle 14 is then rotated so that the plunger

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15, sensor laminate 1 and piercing element 7 move toward the distal end of the syringe 9 extending into the cap 16 so that the piercing element 7 sequentially pierces each divider 18 of each compartment 8 thereby displacing the compartments and releasing the fluids in an ordered sequence to detect any bound target molecule on the sensor laminate 1 (column 9, line 20- column 10, line 54, Figs. 4-6).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al* (USP 4,534,939) or Hessel *et al* (USP 4,534,939) in view of Berger (USP 4,269,237) .

Smith *et al* and Hessel *et al* as previously discussed above, do teach a rupturable membrane for controlling the flow of the material through the cartridge. However, Smith *et al* and Hessel *et al* do not recite the specific use of a ball for closing the opening of a cartridge. However, the use of ball valves is considered conventional in the dispensing art, see Berger.

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Berger device for draining or collecting sump oil from a container, wherein the container has a drain plug closed by a ball valve or rupturable membrane (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have substituted the rupturable membrane means of Smith *et al* or Hessel *et al*, with the ball valve, as taught by Berger. Ball valves are known within the art to provide reliable sealing which can be reused repeatedly.

Response to Arguments

10. Applicant's arguments with respect to claims 1-3, 7-8, 10-12, 19-20, have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

11. Claims 13-18, 23 are allowable.

12. The following is a statement of reasons for the indication of allowable subject matter: see previous Office Action.

Conclusion

13. Claims 13-18, 23 are allowable. Claim 1-3, 7-8, 10-12, 19-20, 22 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-

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7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
February 24, 2003

Jill Warden
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